ANNEX E TO DOD SMALLPOX RESPONSE PLAN 14 Jun 2002
COMMUNICATIONS PLANS AND ACTIVITIES.

REFERENCES.

a. CDC Interim Smallpox Response Plan, Guide E, Communications Plans and Activities, 23 Jan 02.
http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/GuideE/Guide-E.doc.

b. United States Army. Army Crisis Communications Preparation Guide. Washington, DC: January 1999. http://www.dtic.mil/armylink/apac/Documents/crisiscommguide.pdf.

1. General. This DoD Annex implements reference a. Appendix E-1 summarizes CDC Guide E and this DoD Annex on one page.

a. Mission: Public affairs officers (PAOs) throughout DoD will inform and educate relevant audiences about smallpox infection, its symptoms, and consequences. PAOs will also educate relevant audiences about important health strategies to prevent and control smallpox (e.g., vaccination, contact tracing, isolation). Further, PAOs will support and augment the Centers for Disease Control & Prevention's Joint Information Center (JIC), to respond to media queries relating to military support to civilian authorities.

b. Assumption: The first suspected or confirmed case of smallpox will generate intensive local, regional, state, national, and international media interest. Dealing with a smallpox outbreak will require extensive communications activities among numerous government agencies.

c. Background: Reference a outlines CDC plans and activities before and after a smallpox outbreak. This plan reflects CDC goal of synchronizing messages from federal agencies ("speaking with one voice"). Reference b provides suggestions for developing installation communications plans for dealing with emergency situations.

2. Communications Objectives.

a. To instill and maintain public confidence in the DoD leadership's credibility, its healthcare system, and its ability to work in coordination with civilian authorities to respond to, and manage, a smallpox outbreak. Public messages from DoD will provide accurate, rapid, and complete information to educate, calm fears, and maintain public order.

b. To minimize, as much a possible, public panic and fear related to smallpox.

c. To rapidly provide the public, healthcare providers, policymakers, and the media access to accurate, consistent, and comprehensive information about smallpox, smallpox vaccine, and the management of the situation.

d. To address, as quickly as possible, rumors, inaccuracies, and misperceptions.

e. To provide accurate, consistent, and highly accessible information and materials through the coordination of communication efforts with other federal, state, and local partners.

3. Strategies.

a. Support timely and aggressive education for military members, DoD civilians, retirees, and their families about smallpox.

b. Ensure the public and media perceive that the military and public health systems are prepared for such contingencies and are working to treat those affected and to contain the disease.

c. Ensure all services have credible and trained spokespersons to answer media, Congressional, and public queries related to the military's support of the CDC's efforts.

d. Encourage media and other interested parties with questions to use DoD and CDC websites (e.g., www.bt.cdc.org).

e. Leverage all DoD communications tools and products to support the CDC's efforts and to educate the various publics.

f. Decentralize information to the lowest level, empowering local commands to provide answers to media and other public inquiries about the military's support of CDC's efforts as well as the military's handling of any cases that occur on military installations.

4. Communication Challenges and Threats. To address these challenges, specific communication tools have been and will be developed (Appendix E-2). The Military Vaccine Office will develop message maps to guide future communications.

a. Identifying source of outbreak.

b. The subtle differences between quarantine, isolation, and restriction of movement.

c. The purpose of contact tracing and surveillance.

d. Prioritization for immunization priorities.

e. Counteracting misinformation, controlling rumors and minimizing alarm.

5. Primary Audiences and Stakeholders.

a. U.S. military personnel, including active duty, reserve components, civilians and contractors.

b. Family members and other healthcare beneficiaries.

c. DoD leadership.

d. Congress and the Executive Branch.

e. Government civilian agencies that respond to terrorist events.

f. American public via public media.

6. Responsibilities:

a. Office of the Assistant Secretary of Defense (Public Affairs).

(1) Provide Public Affairs Guidance (PAG), including expected questions and answers.

(2) Respond to incoming media inquiries on DoD-wide policy issues.

(3) Coordinate media interviews with DoD personnel and subject matter experts.

b. Services' Chief of Public Affairs Office.

(1) Prepare and distribute press releases, in coordination with DoD if an outbreak develops and as it progresses. Additional involvement needed for outbreaks directly affecting military installations.

(2) Create and maintain an on-going crisis communications plan.

(3) Create and distribute PAG and other informational products as needed to Services' major commands and other subordinate units.

(4) Prepare advisories and respond to media queries.

(5) Train senior leadership to respond to smallpox interview questions.

(6) Post appropriate messages/articles about smallpox on the Service websites.

(7) Support smallpox education efforts in Service command information products and ensure all products include the CDC's website: www.bt.cdc.org.

c. Public Affairs Offices Supporting the Service Surgeons General.

(1) Provide PAG and all other products to Service Medical Department family PAOs, to assist in answering media queries.

(2) Encourage each Military Treatment Facility (MTF) commander to act as a media spokesperson and/or to identify a subject matter expert for local media queries.

(3) Coordinate with DoD agencies and CDC subject matter experts to respond to requests for interviews.

(4) Design or modify websites with smallpox information, updates, fact sheets, frequently asked questions and answers, and healthcare provider resources, including patient and public education materials. DoD's Military Vaccine Office is coordinating this work now, in advance of any outbreak.

(5) Monitor public media for articles and inform leadership of stories that have high impact on the medical department(s).

(6) Provide public-affairs advice to all agencies that request assistance.

d. Installation Public Affairs Offices.

(1) Identify PAO representatives to augment the CDC's Joint Information Center once established.

(2) Respond quickly and accurately to requests for information about the military's support of CDC.

(3) Use all available command information tools to educate the public on smallpox.

(4) Establish contact with the CDC's Field Communications Media Liaison, who will serve as the principal CDC media advisor in the field, and assist the CDC smallpox response team leader in serving, as appropriate, as a media spokesperson.

(5) Design or modify websites with smallpox information, updates, fact sheets, frequently asked questions and answers, and healthcare provider resources, including patient and public education materials. Support for this effort will come from DoD's Military Vaccine Office.

(6) Monitor public media for articles and inform leadership of stories that have high impact on the medical command.

(7) Provide public affairs advice to all agencies that request assistance.

e. Healthcare providers: Augment their own knowledge of smallpox disease and smallpox vaccination, to ensure their ability to answer soldiers' questions and relieve anxiety.

APPENDIX E-1
Communications Plans and Activities – Summary.

1. The Office of the Assistant Secretary of Defense (Public Affairs) will:

a. Provide Public Affairs Guidance (PAG), including questions and answers.
b. Respond to incoming media inquiries on DoD-wide policy issues.
c. Coordinate media interviews with DoD personnel and subject matter experts.

2. Service Public Affairs Offices will:

a. Prepare and distribute press releases.
b. Create and maintain an on-going crisis communications plan.
c. Create and distribute PAG and informational products commands and units.
d. Prepare advisories and respond to media queries.
e. Train senior leadership to respond to smallpox interview questions.
f. Post appropriate messages or articles about smallpox on Service websites.
g. Support smallpox education efforts in Service command information products.

3. Public Affairs Offices Supporting the Service Surgeons General will:

a. Provide PAG and other products to Service Medical Department family PAOs.
b. Encourage commanders to identify subject matter expert for media queries.
c. Coordinate with DoD agencies and CDC experts to respond to requests.
d. Design or modify websites to provide smallpox information.
e. Monitor public media for articles and inform leadership of relevant stories.
f. Provide public-affairs advice to all agencies that request assistance.

4. Installation Public Affairs Offices will:

a. Identify PAO representatives to augment the CDC's Joint Information Center.
b. Respond accurately to requests for information about the military's role.
c. Use command information tools to educate the public on smallpox.
d. Establish contact with the CDC's Field Communications Media Liaison.
e. Design or modify websites to provide smallpox information.
f. Monitor public media for articles and inform leadership of relevant stories.
g. Provide public affairs advice to all agencies that request assistance.

APPENDIX E-2
Common Questions & Answers.

1. For the General Public.

a. Smallpox - The Disease.

b. Smallpox - Vaccine Overview.

c. Smallpox - Vaccine Effectiveness.

d. Smallpox Vaccine - Safety.

e. Smallpox In The Environment.

2. For Health-Care Providers.

a. Smallpox Vaccine Safety - Health-care Providers (HCP).

b. How To Administer Smallpox Vaccine - HCP.

c. Treating Complications Of Smallpox Vaccination - HCP.

d. Evidence Of Immunity And Vaccination-Response Interpretation - HCP.

e. Vaccination Site Care - HCP.

f. Infection-Control Measures.

g. Decontamination.

3. Other Sources of Information for the Public.

a. World Health Organization.
www.who.int/emc/diseases/smallpox/factsheet.hml

b. Centers for Disease Control & Prevention.
www.bt.cdc.gov/DocumentsApp/FAQSmallpox.asp?link=2&page=bio

c. Infectious Disease Society of America.
http://immunizationinfo.org/search/results2.cfm?id=26

1. a. Smallpox - The Disease.

What is smallpox?

Smallpox is a very serious disease. Smallpox is caused by a virus called variola, which spreads from person to person through prolonged face-to-face contact. Indirect spread is less common.

Smallpox can cause:

- A severe rash covering the whole body that can leave permanent scars.
- High fever.
- Severe headache or backache.
- Death (in about 30% of infected people).
- Blindness in some survivors.

Natural cases of smallpox have been eradicated from the Earth. The last natural case of smallpox was in 1978.

The incubation period for smallpox is about 12 to 14 days (range: 7 to 17 days) after exposure. Initial symptoms include high fever, fatigue, headache, and severe back pain.

A characteristic rash, notably on the face, arms, and legs, follows 2 to 3 days later. The rash starts with flat red lesions that progress at the same rate. These lesions fill with pus and begin to crust early in the second week. Scabs develop, then separate, and fall off after about 3 to 4 weeks.

Is smallpox fatal?

Most patients infected with smallpox recover. Smallpox kills about 3 out of 10 people infected. Many smallpox survivors have permanent scars over large areas of their body, especially their face. People who survive smallpox have lifelong immunity against getting smallpox a second time.

Is smallpox contagious? How does smallpox spread?

People are most infectious during the first week of the rash, because that is when the largest amount of virus is present in saliva. However, some risk of transmission lasts until all scabs fall off.

The most common way to transmit smallpox would be from person-to-person. People infected with smallpox exhale little droplets that carry the virus to the nose or mouth of bystanders. The greatest risk comes from prolonged face-to-face contact (6 feet or less) for 3 or more hours, with an infected person, especially one who is coughing. Indirect

contact is less efficient at spreading the virus, but it still occurred via fine-particle aerosols or inanimate objects (i.e., fomites) carrying the virus.

Contaminated clothing or bed linen could spread the virus. Special precautions need to be taken to thoroughly clean all bedding and clothing of smallpox patients with bleach and hot water. Disinfectants such as bleach or ammonia can be used for cleaning contaminated surfaces.

Smallpox is not spread by animals or insects. Smallpox is not spread by food or water.

1. b. Smallpox - Vaccine Overview.

What is smallpox vaccine?

The smallpox vaccine does not contain smallpox virus, so the name of the vaccine is a bit confusing. Smallpox vaccine contains a live virus called vaccinia. It is more technically correct to call smallpox vaccine by the name “vaccinia vaccine,” but "smallpox vaccine" is more commonly used. Vaccinia is sometimes called “cowpox.”

Vaccinia virus is similar to the smallpox (variola) virus. Edward Jenner reported in 1796 that people given vaccinia (smallpox) vaccine become protected from smallpox. Smallpox vaccine was the very first vaccine and has been used successfully for over 205 years.

Getting smallpox vaccine *before* exposure will protect most people from smallpox. Getting the vaccine *within 4 days after exposure* may prevent the disease or make it less severe. Getting the vaccine *within a week after exposure* may still make the disease less severe. Immunity after vaccination lasts about 10 years. People who received several doses of smallpox vaccine may be protected for longer periods of time.

Why get vaccinated?

Smallpox vaccination is the best way to avoid being infected with smallpox. Until the late 1970s, many billions of people around the globe received smallpox vaccine. Smallpox vaccine is still used routinely to protect a small number of people who work with vaccinia virus or similar viruses.

Authorities are concerned that terrorists or governments hostile to the United States may have some of the variola virus that causes smallpox disease. If so, they could use it as a biological weapon in bombs or sprays or by other methods. People exposed to variola virus, or those at risk of being exposed, can be protected by vaccinia (smallpox) vaccine.

There is no proven treatment for the smallpox disease, but research to evaluate new antiviral medications is ongoing. Patients with smallpox can benefit from supportive therapy (e.g., intravenous fluids, medicine to control fever or pain) and antibiotics for any secondary bacterial infections that occur from all the skin problems smallpox causes.

Who should get smallpox vaccine and when?

Who: Routine non-emergency users include laboratory workers who handle cultures or animals infected with vaccinia or other orthopox viruses (e.g., monkeypox, cowpox, variola). Other health-care workers who handle materials (e.g., dressings) that may be contaminated with vaccinia virus should also be vaccinated.

When: These at-risk workers should get one dose of smallpox vaccine before the risk of exposure begins. In general, they should get revaccinated every 10 years.

Who: Bioterrorism could result in people being exposed to the variola virus. These people would go on to develop smallpox disease, further exposing their close contacts, those involved in their medical care or transportation, and lab personnel who collect or process specimens from smallpox patients. Vaccination of other selected groups (e.g., medical, law enforcement, emergency response, military) may be recommended by public-health authorities.

When. One dose of smallpox vaccine, before imminent release of virus for those at high risk of exposure, or one dose as soon as possible after release of virus for those exposed to or at risk of contact with patients or virus.

How long has smallpox vaccine been around?

Smallpox vaccination was the very first vaccination. Edward Jenner first developed it in 1796.

1.c. Smallpox - Vaccine Effectiveness.

If I get vaccinated against smallpox, how protected will I be?

The effectiveness of the vaccine has never been measured precisely in controlled trials. But smallpox vaccination was so successful that it eradicated the natural form of the disease from planet Earth. Scientists estimate that about 95% of vaccine recipients are protected from smallpox.

If people got smallpox vaccination in the past, when it was used routinely, will they still be immune?

Immunity decreases with the passage of years. In the United States, routine vaccination against smallpox ended around 1972 in most places. Military smallpox vaccination programs continued longer. In 1984, routine military vaccinations were limited to recruits entering basic training. Between 1984 and 1989, some service members were immunized but not others. In 1990, the Department of Defense discontinued routine vaccination of recruits.

The level of immunity, if any, among people vaccinated more than 10 years ago is uncertain. Therefore, these people are assumed to be susceptible. For those who were vaccinated, it is not known how long immunity lasts. The more doses of smallpox vaccine a person received in a lifetime, the longer immunity is likely to persist. Even if immunity wanes, vaccinated people shed fewer viruses and are less likely to transmit smallpox than unvaccinated people.

One way to measure how long immunity lasts is to look at the chance of dying from smallpox if one is infected with smallpox. This was calculated in Europe several decades ago.

Risk of dying:
58% in unvaccinated adults (28 out of 48 unvaccinated adults infected).
11% in people vaccinated 21 or more years earlier.
7% in people vaccinated 11 to 20 years earlier.
1.4% in people vaccinated 1 to 10 years earlier.

(Mack TM. Smallpox in Europe, 1950-1971. *Journal of Infectious Diseases* 1972;125:161-9.)

Who received the smallpox vaccination in the past?

Most Americans more than 30 years old were vaccinated against smallpox 20 or more years ago. Most Americans younger than 30 years old have never been vaccinated against smallpox.

Most American civilians born before 1972 have gone 20 or more years since their last smallpox vaccination. Those born since 1972 who never served in the US military probably never got smallpox vaccination.

How often should somebody get smallpox vaccination?

Most estimates suggest immunity from smallpox vaccination is almost complete for 3 to 10 years. Immunity can be boosted effectively with a single revaccination at an interval based on level of risk.

1. d. Smallpox Vaccine - Safety.

Is smallpox vaccine safe?

Most people who get smallpox vaccine have no complications. But smallpox vaccine is not completely safe. Rarely, smallpox vaccination can lead to serious complications. About 1 out of 1,000,000 smallpox vaccine recipients will die as a result of this vaccination. Like all vaccines, smallpox vaccine can cause the usual temporary side effects (e.g., swelling at the vaccination site).

Smallpox vaccine does not contain variola virus, so it cannot cause smallpox. Smallpox vaccine contains live vaccinia viruses, which cross-protect against variola viruses.

Why should I take this vaccine?

People in many countries are concerned about the potential use of smallpox as a bioterrorism agent. The likelihood that smallpox would be used as a bioweapon is unknown. About 30 percent of people who contract smallpox die; about 70% survive.

Vaccination prevents almost all cases of smallpox. If symptoms of smallpox do appear, they are generally milder than in unvaccinated people.

What are the temporary side effects after smallpox vaccination?

As with all vaccines, side effects can result from smallpox vaccination. Mild to moderate problems include a possible blister, which may later form a scar, at the vaccination site. This is an expected reaction. Swelling and tenderness of lymph nodes can last 2 to 4 weeks after the blister heals. About 70% of vaccinated children can get a fever of over 100°F, and 15% to 20% of children can get a fever of over 102°F. About five per 10,000 people may have blisters away from the vaccination site. Some individuals may have rashes that last 2 to 4 days. These side effects are usually temporary and self-limiting, meaning they go away on their own or with minimal medical treatment (e.g., aspirin, rest).

What are the serious side effects after smallpox vaccination?

Moderate to severe reactions are also possible. About 2 to 3 per 10,000 people may have vaccinia rashes on their bodies. These rashes may be more common among toddlers, children 1 to 4 years of age. About four per 10,000 can have severe eczema (a kind of skin inflammation).

Encephalitis or neurologic problems can occur in about one per 100,000 people. Severe infection beginning at the vaccination site can occur in 1 to 2 per million people.

Death can result from about 1 per 1,000,000 people vaccinated against smallpox. The greatest risk of death occurs with people with suppressed immune systems.

Can someone vaccinated against smallpox infect someone else?

Adverse reactions, sometimes severe, can also occur in people who come in contact with a vaccinated person. These problems result from touching the vaccination site and transferring vaccinia viruses to another person. More information on this appears below.

Are there any medical conditions that would bar me from taking the smallpox vaccine?

If you have one of the following medical conditions, you should not receive smallpox vaccine, unless you have been exposed to someone who is actually infected with smallpox. These medical conditions include eczema, a past history of eczema, a suppressed immune system (e.g., AIDS, cancer), or taking a medication that suppresses the immune system. Also, if you have certain skin conditions (e.g., allergic rash, burns, impetigo, or chickenpox) or are moderately ill, you discuss your options with a physician. If possible, wait until your condition clears up before getting the smallpox vaccine. Again, these bars to vaccination may not apply in an emergency. Consult your physician.

What if I am pregnant or breast-feeding?

As with most vaccines, vaccination of pregnant women should be deferred unless it is clearly needed. Live-viral vaccines are usually barred (contraindicated) during pregnancy. But if you have been exposed to smallpox, you would probably be vaccinated against it. Smallpox vaccine is not known to cause birth defects. On very rare occasions, vaccinia infection of the fetus has been reported after vaccinating the mother. This fetal vaccinia infection may result in stillbirth or death of the infant soon after delivery. About 50 of these fetal cases have been recorded after vaccinating literally billions of women around the globe.

Smallpox infection among pregnant women has been reported to result in a more severe infection than among nonpregnant women. Therefore, the risks to the mother and fetus from smallpox infection clearly outweigh any potential risks resulting from vaccination. In addition, vaccinia virus has not been found to cause birth defects, and the incidence of fetal vaccinia is low. When the level of exposure risk is undetermined, the decision to vaccinate should be made after discussion by the clinician and patient of the potential risks versus the benefits of smallpox vaccination.

Breast-feeding is not a bar (contraindication) to any vaccination. Vaccination has not effect on the breast-feeding mother, nor the breast-fed child.

What other medical conditions should I inform the medical staff about?

If you have had a life-threatening reaction to polymyxin B, streptomycin, chlortetracycline, neomycin or a previous dose of smallpox vaccine, it may not appropriate to get vaccinated. Talk with your physician.

1. e. Smallpox In The Environment.

Do tests exist to show if smallpox is in the environment, like tests for anthrax?

Various agencies are currently developing tests designed to test for the smallpox virus in the environment. Like all tests of their kind, these tests can generate both false-positive results (test says positive, but it's really negative) and false-negative tests (test says negative, but it's really positive). These tests must be interpreted carefully by experienced laboratory professionals.

If smallpox is discovered or released in a building, or if a person develops symptoms in a building, how can that area be decontaminated?

The smallpox virus is very fragile. If smallpox virus is released into the air, all viruses will be naturally inactivated or dissipated within 1 to 2 days. Buildings exposed to the initial aerosol release of the virus do not need to be decontaminated. By the time the first cases are identified, typically 2 weeks after the release, the virus in the building will be gone. Infected patients, however, will be capable of spreading the virus and possibly contaminating surfaces while they are sick. Scabs can transmit smallpox virus, but this is unusual.

Standard hospital-grade disinfectants such as quaternary-ammonia compounds are effective in killing the virus. They should be used on surfaces to disinfect hospitalized patients' rooms or other contaminated surfaces. Although less desirable because it can damage equipment and furniture, hypochlorite (bleach) is an acceptable alternative. In the hospital setting, patients' linens should be autoclaved or washed in hot water with bleach added. Infectious waste should be placed in biohazard bags and autoclaved before incineration.

What should people do if they suspect a person has smallpox or suspect that smallpox has been released in their area?

On military installations, report suspected cases of smallpox or suspected intentional release of smallpox to your local hospital or clinic. In civilian communities, report suspected cases of smallpox or suspected intentional release of smallpox to your local health department. The hospital, clinic, or local health department will evaluate the situation and make needed reports to higher headquarters, the CDC, and the state health department.

How can we stop the spread of smallpox after someone comes down with it?

The most important steps to stop a smallpox epidemic are case isolation and contact tracing and vaccination.

Patients showing signs of smallpox are capable of spreading the virus. Patients should be placed in medical isolation so that they will not continue to spread the virus. In addition, people who have come into close contact with smallpox patients should be vaccinated immediately and closely watched for symptoms of smallpox. Vaccination and isolation are the key strategies for stopping the spread of smallpox.

2. For Health-Care Providers.

2. a. Smallpox Vaccine Safety - Health-Care Providers (HCP).

Besides the normal side effects covered already, is there more information I need to know as a health-care provider?

Inadvertent inoculation at other sites is the most frequent complication of vaccinia vaccination. It accounts for about half of all complications of primary (first) vaccination and revaccination. Inadvertent inoculation usually results from auto-inoculation of vaccinia virus, transferred from the site of vaccination. The most common sites involved are places that itch: the face, eyelids, nose, mouth, genitalia, and rectum.

Most auto-inoculation lesions heal without specific therapy, but vaccinia immune globulin (VIG) can help treat cases of ocular implantation. However, if vaccinial keratitis is present, VIG is barred (contraindicated) because it might increase corneal scarring.

Erythematous or urticarial rashes can occur about 10 days after primary (first) vaccination and can be confused with generalized vaccinia. However, the vaccinee is usually afebrile with this reaction, and the rash resolves spontaneously within 2 to 4 days. Rarely, bullous erythema multiforme (i.e., Stevens-Johnson syndrome) occurs.

What about moderate to severe adverse reactions?

Moderate and severe complications of vaccinia vaccination include eczema vaccinatum, generalized vaccinia, progressive vaccinia, and postvaccinial encephalitis. These complications are rare, but occur at least 10 times more often among primary vaccinees than among revaccinees. These serious skin complications also are more frequent among infants than among older children and adults. A study of Israeli military recruits aged 18 years or older, who were vaccinated during 1991 and 1996, reported rates of progressive vaccinia (0 out of 10,000 vaccinees) and postvaccinial encephalitis (0 out of 10,000 vaccinees) similar to those reported in previous studies.

What is eczema vaccinatum?

Eczema vaccinatum is a localized or systemic dissemination of vaccinia virus among people who have eczema or a history of eczema or other exfoliative skin conditions (e.g., atopic dermatitis). Usually, this illness is mild and self-limited, but can be severe or fatal. The most serious cases among vaccine recipients occur among primary vaccinees, even among people who do not have active eczema. Severe cases have been observed after recently vaccinated people had contact with people with active eczema or a history of eczema.

What is generalized vaccinia?

Generalized vaccinia involves a vesicular rash of varying extent that can occur among people without underlying illnesses. The rash is generally self-limited and requires minor or no therapy, except among patients whose conditions might be toxic or who have serious underlying immunosuppressive illnesses (e.g., acquired immunodeficiency syndrome [AIDS]).

What is progressive vaccinia?

Progressive vaccinia (also called vaccinia necrosum or vaccinium gangrenosa) is a severe, potentially fatal illness. It appears as progressive necrosis reaching out from the vaccination site, often with metastatic lesions. It occurred almost exclusively among people with cellular immunodeficiency.

What is postvaccinial encephalitis?

The most serious complication is postvaccinial encephalitis. Two main forms were noted. The first affected children younger than 1 year old receiving their first (primary) smallpox vaccination, involving convulsions. These children may have residual paralysis after recovery.

The second form affected children 2 years or older, adolescents, and adults receiving a their first (primary) smallpox vaccination. These patients developed abrupt onset of fever, vomiting, headache, and malaise, followed by loss of consciousness, amnesia, confusion, convulsions, and coma. About 1 in 3 of these patients died.

How often this complication occurred varies with the strain of vaccinia virus and was higher in Europe than in the United States. The principal strain of vaccinia virus used in the United States, the New York City Board of Health (NYCBOH) strain, was associated with the lowest incidence of postvaccinial encephalitis. About 15% to 25% of affected vaccinees with this complication die, and 25% have permanent neurological sequelae. Fatal complications caused by vaccinia vaccination are rare, with approximately 1 death per 1,000,000 primary vaccinations and 1 death per 4,000,000 revaccinations. Death most often results from postvaccinial encephalitis or progressive vaccinia.

Who is barred (contraindicated) from smallpox vaccine?

No absolute bars (contraindications) exist for vaccination of a person with a high-risk exposure to smallpox. People at greatest risk for experiencing serious vaccination complications are also at greatest risk for death if exposed to smallpox.

If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination complications must be weighed against the risk for experiencing a potentially fatal smallpox infection. When the level of exposure risk cannot be determined, the decision to vaccinate should be made after discussion by the clinician and the patient of the potential risks versus the benefits of smallpox vaccination.

2. b. How To Administer Smallpox Vaccine - HCP.

Vaccination has been successfully and safely administered to people of all ages, from birth onward. As with all vaccinations, the smallpox vaccination process should begin with careful individualized assessment of vaccine indications and contraindications.

The skin over the insertion of the deltoid muscle or the posterior aspect of the arm over the triceps muscle are the preferred sites for smallpox vaccination. Alcohol or other chemical agents are not required for skin preparation for vaccination, unless the area is grossly contaminated. If alcohol is used, the skin must be allowed to dry thoroughly (requiring several minutes) to prevent inactivation of the vaccine by the alcohol. Acetone dries more quickly.

The multiple-puncture technique uses a presterilized bifurcated needle inserted vertically into the vaccine vial, causing a droplet of vaccine to adhere between the prongs of the needle. The droplet contains the recommended dosage of vaccine. Confirm the presence of the droplet between the prongs of the bifurcated needle visually. Holding the bifurcated needle perpendicular to the skin, make 15 punctures rapidly, with strokes vigorous enough to allow a trace of blood to appear after 15 to 20 seconds. Wipe off any remaining vaccine with dry sterile gauze, then dispose of the gauze in a biohazard waste container.

Cover the site with a loose, nonocclusive bandage to deter the individual from touching the site and perhaps transferring virus to other parts of the body. Alternately, the site can be left uncovered, if the individual is thoroughly counseled about the hazards of touching the vaccination site.

After about 3 days, a red papule appears at the vaccination site and becomes vesicular on about the fifth day. By the seventh day, it becomes the typical Jennerian pustule--whitish, umbilicated (sunken center), multilocular, containing turbid lymph and surrounded by an erythematous (reddened) areola (circle) that may continue to expand for 3 more days. Swollen lymph nodes nearby and fever are not uncommon. As many as 70% of children have 1 or more days of temperature higher than 39°C (100°F) between days 4 and 14. The pustule (pus-filled blister) gradually dries, leaving a dark crust, which normally falls off after about 3 weeks.

A successful vaccination for those with some preexisting immunity may manifest a range of responses. These can include what appears to be a primary take (described above) or an accelerated reaction. In an accelerated reaction, there may be little more than a papule (bump) surrounded by erythema (redness) that reaches a peak between 3 and 7 days. A response that reaches a peak in erythema within 48 hours represents a hypersensitivity reaction and does not reflect that growth of the vaccinia virus occurred. People exhibiting a hypersensitivity reaction should be revaccinated.

2. c. Treating Complications of Smallpox Vaccination - HCP.

What treatment can be given to patients who had a reaction to smallpox vaccine?

The only product that was FDA-licensed for treatment of complications of vaccinia vaccination is vaccinia immune globulin (VIG). VIG is an isotonic solution of immunoglobulin G harvested from the plasma of people who received smallpox (vaccinia) vaccine. VIG is effective in treating eczema vaccinatum and some cases of progressive vaccinia.

VIG might be useful also in the treatment of ocular vaccinia resulting from inadvertent implantation. However, VIG is barred (contraindicated) for the treatment of vaccinial keratitis.

VIG is recommended for severe generalized vaccinia, if the patient is extremely ill or has a serious underlying disease. VIG provides no benefit in the treatment of postvaccinial encephalitis and has no role in the treatment of smallpox.

Current supplies of VIG are limited. VIG is currently reserved for treatment of vaccine complications with serious clinical manifestations (e.g., eczema vaccinatum, progressive vaccinia, severe generalized vaccinia, severe ocular implantation).

What is the treatment regimen for using VIG?

The recommended dosage of the currently available VIG for treatment of complications is 0.6 ml/kg of body weight. The original form of VIG must be administered intramuscularly, as early as possible after onset of symptoms. Because therapeutic doses of VIG might be substantial (e.g., 42 ml for a person weighing 70 kg), the product can be administered in divided doses over a 24- to 36-hour period. Doses can be repeated, usually at intervals of 2 to 3 days, until recovery begins (e.g., no new lesions appear).

Newer formulations of VIG will require intravenous administration. Health-care providers should refer to the manufacturer's product labeling for proper dosages and other therapeutic details.

Military healthcare providers may obtain VIG from the US Army Medical Research Institute of Infectious Diseases (USAMRIID), after appropriate consultation with infectious-disease, dermatology, or allergy-immunology specialists. CDC is currently the only source of VIG for civilians.

What about VIG during a smallpox outbreak?

If vaccination of people with bars (contraindications) is required because of exposure to smallpox virus, current stores of VIG are insufficient to allow its prophylactic use along with vaccination. Because of the limited stores of VIG, its use in such a scenario should be reserved for severe, life-threatening complications (e.g., progressive vaccinia, eczema vaccinatum, or severe, toxic generalized vaccinia).

If additional VIG becomes available in sufficient quantities to allow its prophylactic use, VIG should be administered at a dose of 0.3 mg/kg along with smallpox (vaccinia) vaccine to people with bars (contraindications) who require vaccination.

Are there other treatment options for those that have vaccinia vaccine complications?

The Food and Drug Administration has not approved the use of any antiviral compound for the treatment of vaccinia virus infections or other Orthopoxvirus infections, including smallpox (variola infection). Certain antiviral compounds are active against vaccinia virus or other Orthopoxviruses in vitro and among test animals. However, the safety and effectiveness of these compounds for treating vaccinia vaccination complications or other Orthopoxvirus infections among humans is unknown. Questions also remain regarding the effective dose and the timing and length of administration of these antiviral compounds.

Additional information could become available. Health-care providers should consult infectious-disease experts for updated information regarding treatment options for smallpox vaccination complications.

2. d. Evidence of Immunity and Vaccination-Response Interpretation.

After vaccination, what evidence suggests an individual developed immunity against smallpox?

Smallpox vaccination with live vaccinia virus causes the body to produce neutralizing IgG antibodies, as well as vaccinia-specific cell-mediated immunity. In a person with normal immune function, neutralizing antibodies appear about 10 days after primary vaccination and 7 days after revaccination. Clinically, people are considered fully protected after a successful response is demonstrated at the site of vaccination, about 7 days after vaccination.

The vaccination site should be inspected 6 to 8 days after vaccination and the response interpreted at that time. The World Health Organization (WHO) Expert Committee on Smallpox defines two types of responses. The responses include:

(a) a major reaction, which indicates that virus replication has taken place and vaccination was successful; or

(b) an equivocal reaction, which either indicates (1) a possible consequence of immunity adequate to suppress viral multiplication or (2) allergic reactions to an inactive vaccine without production of immunity.

What is a "major reaction"?

Major (i.e., primary) reaction is defined as a vesicular (blister) or pustular lesion or an area of definite palpable induration (hardness) or congestion surrounding a central lesion that might be a crust or an ulcer. The usual progression of the vaccination site after primary vaccination is as follows:

a. The inoculation site becomes reddened and itchy 3 to 4 days after vaccination.

b. A vesicle (blister) surrounded by a red areola then forms, which becomes umbilicated (sunken center) and then pustular (pus-filled) by days 7 to 11 after vaccination.

c. The pustule begins to dry, the redness subsides, and the lesion becomes crusted between the second and third week.

d. By the end of about the third week, the scab falls off, leaving a permanent scar that at first is pink in color, but eventually becomes flesh-colored.

Skin reactions after revaccination might be less pronounced with more rapid progression and healing than those after primary vaccinations. Revaccination is considered successful if a pustular lesion is present or an area of definite induration or congestion surrounding a central lesion (i.e., scab or ulcer) is visible upon examination 6 to 8 days after revaccination.

What is an "equivocal reaction"?

Equivocal reactions consolidate a variety of previous terms, including accelerated, modified, vaccinoid, immediate, early, or immune reactions. Equivocal reactions are defined as all responses other than major reactions.

If an equivocal reaction is observed, check vaccination procedures and repeat the vaccination by using vaccine from another vial or vaccine lot, if available. It is often difficult to determine if the reaction was blunted by immunity, insufficiently potent vaccine, or vaccination technique failure. If the repeat vaccination using different vaccine fails to elicit a major reaction, health-care providers should consult CDC or their state or local health department before attempting another vaccination.

2. e. Vaccination Site Care - Health-Care Providers

Is it true that the virus can be transmitted from recently vaccinated people?

Transmission of vaccinia virus can occur when a recently vaccinated person has contact with a susceptible person. In a 1968 10-state survey of complications of vaccinia vaccination, the risk for transmission of vaccine virus to contacts was 27 infections out of 1,000,000 vaccinations; 44% of those contact cases occurred among children aged 5 years or younger.

Before the U.S. military discontinued routine smallpox vaccination in 1990, occurrences of contact transmission of vaccinia virus from recently vaccinated military recruits had been reported, including six cases resulting from transmission from one vaccine recipient.

Are there precautions I can take as a health-care provider to help my patients avoid spreading vaccinia to others?

Vaccinia virus can be found at the site of primary vaccination beginning at the time of development of a papule (i.e., 2 to 5 days after vaccination) until the scab separates from the skin lesion (i.e., 14 to 21 days after vaccination). During that time, care must be taken to prevent spread of the virus to another area of the body or to another person by inadvertent contact.

Perform thorough hand-hygiene with soap and water or disinfecting agents after direct contact with the site, as well as materials that came into contact with the site. This will help remove virus from the hands and prevent accidental inoculation to other areas of the body. In addition, take care to prevent unvaccinated people from having contact with the site or contaminated materials from the site.

The vaccination site can be left uncovered, or it can be loosely covered with a porous bandage (e.g., gauze) until the scab separates on its own, to provide additional barrier protection against inadvertent inoculation. An occlusive bandage should not be routinely used because maceration (prolonged soaking that can lead to break down) of the site might occur. Change bandages used to cover the vaccination site frequently (i.e., every 1 to 2 days), to prevent maceration of the site from fluid buildup. Use hypoallergenic tape for people who experience tape hypersensitivity.

Keep the vaccination site dry, although normal bathing can continue. No salves or ointments should be placed on the vaccination site. Place contaminated bandages and, if possible, the vaccination site scab, after it has fallen off, in sealed plastic bags. Dispose of this waste in the trash to further decrease the potential for inadvertent transmission of the live virus contained in the materials. Clothing or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with bleach.

If I must continue care of patients, what I can do to protect them from the viruses at my recent vaccination site?

Recently vaccinated health-care workers should avoid contact with unvaccinated patients, particularly those with immunodeficiencies, until the scab separates from the skin at the vaccination site. However, if continued contact with unvaccinated patients is unavoidable, health-care workers can continue to have contact with patients, including those with immune deficiencies, as long as the vaccination site is well-covered and thorough hand-hygiene is maintained.

In this setting, a more occlusive dressing might be required. Semipermeable polyurethane dressings (e.g., Opsite®) are effective barriers to vaccinia and recombinant vaccinia viruses. However, exudates can accumulate beneath the dressing, and care must be taken to prevent viral contamination when the dressing is removed. In addition, accumulation of fluid beneath the dressing can increase the maceration of the vaccination site. Accumulation of exudates can be decreased by first covering the vaccination site with dry gauze, then applying the dressing over the gauze. The dressing should also be changed at least once a day. To date, experience with this type of containment dressing has been limited to research protocols.

The most critical measure in preventing inadvertent implantation and contact transmission from vaccinia vaccination is thorough hand-hygiene after changing the bandage or after any other contact with the vaccination site.

2.f. Infection-Control Measures.

Should smallpox patients be isolated? What precautions should be taken by the hospital or clinic?

Isolation of confirmed or suspected smallpox patients will be necessary to limit the potential exposure of unvaccinated and, therefore, nonimmune people. Although droplet spread is the major mode of person-to-person smallpox transmission, airborne transmission through fine-particle aerosol can occur. Therefore, initiate airborne precautions using correct ventilation (e.g., negative air-pressure rooms with high-efficiency particulate air filtration) for hospitalized confirmed or suspected smallpox patients, unless the entire facility has been restricted to smallpox patients and recently vaccinated people.

Recently vaccinated people who demonstrated an immune response should be fully protected against infection with variola virus. Nonetheless, continue to observe standard and contact precautions (i.e., using protective clothing and shoe covers) when in contact with smallpox patients or contaminated materials, to prevent inadvertent spread of variola virus to susceptible people and potential self-contact with other infectious agents.

Personnel should remove and correctly dispose of all protective clothing before contact with unvaccinated people. Reuseable bedding and clothing can be autoclaved or laundered in hot water with bleach to inactivate the virus. Laundry handlers should be vaccinated before handling contaminated materials.

What about other facilities (i.e., individual homes)?

Nonhospital isolation of confirmed or suspected smallpox patients should be of a sufficient degree to prevent the spread of disease to nonimmune people during the time the patient is considered potentially infectious (i.e., from onset of fever until all scabs separate). Private residences or other nonhospital facilities used to isolate confirmed or suspected smallpox patients should have nonshared ventilation, heating, and air-conditioning systems. Limit access to those facilities to recently vaccinated people with a demonstrated immune response. If suspected smallpox patients are placed in the same isolation facility, vaccinate them to guard against accidental exposure caused by misclassification as someone with smallpox.

In addition to isolation of infectious smallpox patients, start fever surveillance of contacts during their potential incubation period. Transmission of smallpox virus rarely occurs before the appearance of the rash that develops 2 to 4 days after the prodromal fever. If a vaccinated or unvaccinated contact experiences a fever of 101°F (38°C) or higher during the 17-day period after his or her last exposure to a smallpox patient, the contact should be isolated immediately to prevent contact with unvaccinated or nonimmune people until smallpox can be ruled out by clinical or laboratory examination.

What other procedures and considerations should medical communities be aware of?

As soon as the diagnosis of smallpox is made, immediately isolate all individuals in whom smallpox is suspected. Vaccinate all household and other prolonged face-to-face contacts and place them under fever surveillance. Because the widespread dissemination of smallpox virus by aerosol poses a serious threat in hospitals, isolate patients in the home or other nonhospital facility whenever possible. Home care for most patients is a reasonable approach, given the fact that little can be done for a patient other than to offer supportive therapy.

In the event of an aerosol release of smallpox and a subsequent outbreak, the rationale for vaccinating patients suspected to have smallpox at this time is to ensure that some with a mistaken diagnosis are not placed at risk of acquiring smallpox. Vaccination administered within the first few days after exposure may prevent or significantly reduce subsequent illness. An emergency vaccination program is also indicated for health-care workers at clinics or hospitals that might receive patients, essential disaster-response personnel, and mortuary staff. Personnel for whom vaccination is not barred (contraindicated) should be vaccinated immediately regardless of prior vaccination status.

Vaccination administered within 4 days of first exposure offers some protection against acquiring infection and significant protection against a fatal outcome. Those who have been vaccinated at some time in the past will normally exhibit an accelerated immune response. Thus, it would be prudent, when possible, to assign those who had been previously vaccinated to duties involving close patient contact.

Use discretion used in identifying contacts of patients to focus vaccination and fever surveillance measures on those at greatest risk. People do not transmit smallpox until after the fever gives way to rash.

Contacts, even if infected, are not contagious until onset of rash. So, a practical approach is to have contacts check their temperatures at least once each day, preferably in the evening. Any increase in temperature higher than 38°C (101°F) during the 17-day period after last exposure to the case suggests possible development of smallpox. In such a case, isolate the patient immediately, preferably at home, until it could be determined clinically and/or by laboratory examination whether the contact has smallpox. All close contacts of the patients should be promptly vaccinated.

2. g. Decontamination.

Vaccinia virus, if released as an aerosol and not exposed to ultraviolet (UV) light, may persist for as long as 24 hours or somewhat longer under favorable conditions. Variola virus is believed to exhibit similar properties.

By the time patients become ill with smallpox (12 to 14 days after exposure), there would be no viable smallpox virus remaining in the environment. Vaccinia virus, if released as an aerosol, is almost completely destroyed within 6 hours in an atmosphere of high temperature (31° to 33°C) and humidity (80%). In cooler temperatures (10° to 11°C) and lower humidity (20%), about two-thirds of a vaccinia aerosol survives up to 24 hours. Variola would probably behave similarly.

The occurrence of smallpox infection among personnel who handled laundry from infected patients is well documented, but rare. Variola viruses in such material remain viable for extended periods. Thus, special precautions need to be taken to ensure that all bedding and clothing of smallpox patients is autoclaved or laundered in hot water to which bleach has been added. Disinfectants that are used for standard hospital infection control, such as hypochlorite and quaternary ammonia, are effective for cleaning surfaces possibly contaminated with virus.

Virus in scabs is more durable. At a temperature of 35°C and 65% relative humidity, the virus can persist for 3 weeks. At cooler temperatures (26°C), the virus can survive for 8 weeks at high relative humidity and 12 weeks at a relative humidity less than 10%. Variola virus can be found in scabs sitting on a shelf for 13 years. It is unlikely, however, that the smallpox virus, bound in the fibrin matrix of a scab, is infectious in humans. This

is borne out by studies conducted during the eradication program and by surveillance for cases in newly smallpox-free areas. If the virus were able to persist in nature and infect humans, natural cases would have occurred for a prolonged period after person-to-person disease transmission stopped. But cases of this type were not observed.